CLAIMS

1- An oral self-emulsifying pharmaceutical formulation of a fibrate with improved oral bioavailability comprising a fibrate selected from fenofibrate, derivative of fenofibrate or mixtures thereof dissolved in one or more fibrate solubilizers selected from N-alkyl derivative of 2-pyrrolidone, mono- or di- or polyethylene glycol monoethers, C_{8-12} fatty acid mono- or diesters of propylene glycol, or combinations thereof; and one or more surfactants selected from nonionic, anionic, cationic, and zwitterionic surfactants and combinations thereof; wherein the fibrate to the fibrate solubilizer weight ratio is between about 1:1 and about 1:100.

2 - A formulation according to claim 1 that further contains one or more stabilizers in sufficient amounts to prevent the crystal growth of the fibrate, wherein fibrate remains in solution and no crystallization of fibrate is observed for at least 24 hours.

3 - A formulation according to claim 2 wherein the stabilizers are selected from fatty acids, fatty alcohols, alcohols, long chain fatty acid esters, long chain ethers, hydrophilic derivatives of fatty acids, polyvinylpyrrolidones, polyvinylethers, polyvinyl alcohols, hydrocarbons, hydrophobic polymers, moisture-absorbing polymers.

4 - A formulation according to claim 2 wherein the weight ratio of the fibrate to the stabilizer is between about 50 : 1 to about 1:10.

5 - A formulation according to claim 1 wherein the amount of solubilizers is between about 20% to about 80% by weight of the formulation.

6- A formulation according to claim 1 wherein fibrate solubilizer is selected from N-C_{1-4} alkyl derivative of 2-pyrrolidone, mono- or di- or polyethylene glycol monoethers, C_{8-12} fatty acid mono- or diesters of propylene glycol, or combinations thereof.

7 - A formulation according to claim 1 wherein the surfactant is between about 2% to about 25% by weight of the formulation.

8 - A formulation according to claim 3 wherein the stabilizer is between about 0% to about 30% by weight of the formulation.

9- A formulation according to claims 1 to 8 wherein the solubilizer is selected from N-C_{1-4} alkyl derivative of 2-pyrrolidones, mono- or di- or polyethylene glycol monoethers, C_{8-12} fatty acid mono- or diesters of propylene glycol, or combinations thereof.

10 – A formulation according to claim 9 wherein the weight ratio of the N-C_{1-4} alkyl derivative of 2-pyrrolidone or a mono- or di- or polyethylene glycol monoethers or combinations thereof to one or more C_{8-12} fatty acid mono- or diesters of propylene glycol is between about 100:1 to about 1:100.

11 - A formulation according to claim 9 wherein the solubilizer is C_{8-12} fatty acid monoesters of propylene glycol, C_{8-12} fatty acid diesters of propylene glycol, or combinations thereof.

12 - A formulation according to claim 1 wherein the N-C_{1-4} alkyl derivative of 2-pyrrolidone is selected from N-methyl-2-pyrrolidone, N-ethyl-2-pyrrolidone, N-propyl-

2-pyrrolidone, N-isopropyl-2-pyrrolidone, N-butyl-2-pyrrolidone, and N-(2-hydroxyethyl)-2-pyrrolidone or mixtures thereof.

13 - A formulation according to claim 12 wherein the N-C_{1-4} alkyl derivative of 2-pyrrolidone is N-methyl-2-pyrrolidone.

14 – A formulation according to claim 1 wherein the mono- or di- or polyethylene glycol monoethers is selected from diethylene glycol monoethyl ether, diethylene glycol monobutyl ether, ethyleneglycol monoethyl ether, ethyleneglycol monobutyl ether and other higher-ethylene glycol monoethers.

15 - A formulation according to claim 1 wherein the fibrate solubilizer is a combination of N-methyl-2-pyrrolidone and diethylene glycol monoethyl ether wherein the weight ratios of N-methyl-2-pyrrolidone to diethylene glycol monoethyl ether is between about 100:1 and about 1:100.

16 - A formulation according to claim 9 wherein the stabilizer is ethanol, oleic acid, caprylic acid, capric acid, polyvinylpyrrolidone, waxes, or combinations thereof.

17 - A self-emulsifying oral pharmaceutical formulation with improved bioavailability comprising: a therapeutically effective amount of the fenofibrate or a fenofibrate derivative; at least one surfactant; and one or more fibrate solubilizers selected from N-alkyl derivative of 2-pyrrolidone, mono- or di- or polyethylene glycol monoethers, C_{8-12} fatty acid mono- or diesters of propylene glycol, or combinations thereof; and one or more stabilizers wherein the fibrate to solubilizer weight ratio is between about 1:1 and about 1:100 and the saturation factor is between about

1.05 and about 2.5 and the stabilizer is present in sufficient amounts to prevent crystal growth .

18 – A formulation according to claim 1, 9 or 17 wherein the C_{max} is at least 1.2 times that of Lipanthyl ® or TriCor® or the $AUC_{0-\infty}$ is at least 1.5 times that of Lipanthyl ® or TriCor® when dosed mammals in the fasted state.

19 - A method of treating endogenous hyperlipidaemias, hypercholesterolaemias and hypertriglyceridaemias in mammals comprising the administration of a fibrate formulation of any of claims 1, 9 or 17.

20 – A pharmaceutical dosage unit for oral administration comprising of a fibrate formulation containing a fibrate dissolved in a fibrate solubilizer composed selected from N- alkyl derivative of 2-pyrrolidone, mono- or di- or polyethylene glycol monoethers, C_{8-12} fatty acid mono- or diesters of propylene glycol, or combinations thereof; at least one ionic or non-ionic surfactant or combinations thereof; and optionally one or more stabilizers wherein the fibrate is between about 5 W/W% and about 40 W/W%, the fibrate solubilizer is between about 20 W/W% and about 80 W/W%; the surfactant is about 2 W/W%, and about 25 W/W%; and the stabilizer is between 0 W/W% and 30 W/W%.

21 – An oral self-emulsifying pharmaceutical formulation of a fibrate with improved oral bioavailability comprising a fibrate dissolved in a fibrate solubilizer selected from N-alkyl derivative of 2-pyrrolidone, mono- or di- or polyethylene glycol monoethers, C_{8-12} fatty acid mono- or diesters of propylene glycol, or combinations thereof; at least one ionic or non-ionic surfactant or combinations thereof; and optionally one

or more stabilizers wherein the fibrate is between about 5 W/W% and about 40 W/W%, the fibrate solubilizer is between about 20 W/W% and about 80 W/W%; the surfactant is about 2 W/W%, and about 25 W/W%; the stabilizer is between 0 W/W% and 30 W/W%, the C_{max} is at least 1.2 times that of Lipanthyl ® or TriCor® or the $AUC_{0-\infty}$ is at least 1.5 times that of Lipanthyl ® or TriCor® when dosed mammals in the fasted state.

22 – An oral self-emulsifying pharmaceutical formulation of a fibrate with improved oral bioavailability comprising a fibrate dissolved in a fibrate solubilizer selected from N-alkyl derivative of 2-pyrrolidone, mono- or di- or polyethylene glycol monoethers, C_{8-12} fatty acid mono- or diesters of propylene glycol, or combinations thereof; at least one ionic or non-ionic surfactant or combinations thereof; and optionally one or more stabilizers wherein the fibrate is between about 5 W/W% and about 40 W/W%, the fibrate solubilizer is between about 20 W/W% and about 80 W/W%; the surfactant is about 2 W/W%, and about 25 W/W%; the stabilizer is between 0 W/W% and 30 W/W%, and wherein the saturation factor is between about 1.05 and 2.5.